

Claims

1. A composition for stabilization of protein agents in pharmaceuticals, the composition comprising the following constituents:
 - 5 a) a surface active substance, preferably a non-ionic detergent (tenside),
and
 - b) a mixture of at least two amino acids, wherein the at least two amino acids are either Glu and Gln or Asp and Asn.
- 10 2. The composition according to claim 1, further comprising at least one of the following constituents:
 - c) a disaccharide, preferably sucrose (cane sugar), trehalose or lactose,
 - d) ethylenediaminetetraacetic acid (EDTA), preferably in form of one of its salts such as Na₄-EDTA.
- 15 3. The composition according to claim 1 or 2 comprising the constituents a), b) and c), the constituents a), b) and d) or the constituents a), b), c) and d).
4. The composition according to any one of the preceding claims, wherein the composition is
20 either soluble in aqueous media or is present as aqueous solution.
5. A pharmaceutical composition comprising a protein agent and the composition for stabilization according to any one of the preceding claims.
- 25 6. The pharmaceutical composition according to claim 5, wherein the pharmaceutical composition is present as a freeze-dried or vacuum-dried powder, which is soluble in aqueous media.
7. The pharmaceutical composition according to claim 5 or 6 wherein the protein agent is a
30 coagulation factor such as factor VIII (the antihemophilic globulin), a cytokine such as a interferon, in particular interferon alpha, beta or gamma, an enzyme such as urokinase or streptokinase, a plasminogen activator, or an ultra pure neurotoxin and a neurotoxin complex, respectively, from *Clostridium botulinum*, in particular from *Clostridium botulinum* type A or B.

8. The composition for stabilization according to any one of the claims 1 to 4 or the pharmaceutical composition according to any one of claims 5 to 7, wherein the at least two amino acids are (i) aspartic acid, asparagine, glutamic acid; (ii) aspartic acid, asparagine, glutamine; (iii) aspartic acid, glutamic acid, glutamine; (iv) asparagine, glutamic acid, glutamine; or (v) aspartic acid, asparagine, glutamic acid and glutamine.
9. The composition according to claim 8, wherein the concentrations of the individual amino acids are in each case 20 to 200 mM, more preferred 20 to 100 mM, in particular 50 mM.
10. The composition according to claim 8 or 9, wherein the surface active substance is a non-ionic detergent.
11. The composition according to any one of claims 8 to 10, wherein the non-ionic detergent is a polysorbate such as polysorbate 20 or polysorbate 80 or a poloxamer such as poloxamer 184 or 188.
12. The composition according to any one of claims 8 to 11, wherein the disaccharide is sucrose, trehalose or lactose.
13. The composition according to any one of claims 8 to 12, wherein the pH value of the composition in solution is 5.0 to 8.5, in particular 6.0 to 8.0, preferred at 6.0 to 7.0 and 6.5, respectively.